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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/461,580	12/15/1999	LEONARD GUARENTE	0050.161800	3988
26161	7590	11/15/2005	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			ZEMAN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/461,580

Applicant(s)

GUARENTE ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 169-208 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 169-208 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3-11-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments filed on 9-29-2004 and 8-30-2005 are acknowledged. Claims 169, 176, 181, 185, 193, 209 and 212 have been amended and claims 215-219 have been added as per the 9-29-2004 amendment. Claim 11 has been amended and claims 209-219 have been canceled as per the 8-30-2005 amendment. Claims 11 and 169-208 are pending and currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 3-11-2005 is acknowledged. An initialed copy is attached thereto.

Claim Objections Withdrawn

The objection to claims 185, 193 and 209 for using the abbreviation DTT and failing to define its meaning when first used is withdrawn in light of the amendment to claims 185 and 193 and the cancellation of claim 209.

New Claim Objections

Claim 194 is objected to for containing an obvious typographical error. Sir2 is referred to as SIR2. Appropriate correction is required.

Claim Rejections Withdrawn

The written description rejection of claims 209-214 under 35 U.S.C. 112, first paragraph, is withdrawn. Cancellation of said claims has rendered the rejection moot.

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The rejection of claims 11, 191 and 209 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “the acetylated amino acid side chain” is withdrawn in light of the amendment thereto and the cancellation of claim 209.

The rejection of claim 169 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “the determining” is withdrawn in light of the amendment thereto.

The rejection of claim 176 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “...acetylated at positions corresponding to the lysine amino acid residue is lysine 9 and/or lysine 14 of H3 histone” is withdrawn in light of the amendment thereto.

The rejection of claim 181 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “acetylated amino acid side” is withdrawn in light of the amendment thereto.

New Grounds of Rejection

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re*

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Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 171, 173, 179, 181-185, 188-189, 191-194 and 207-208 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 118-130 of copending Application No. 19/735,786. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to methods of evaluating the deacetylation of a substrate utilizing a protein **comprising** the Sir2 core domain while the claims of the instant application are drawn to the same methods utilizing the full length Sir2 protein. Consequently, since all of the claims of the copending application recite open language with regard to the "Sir2 core domain" they necessarily encompass the full length Sir2 protein recited in the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 169-190, 194-206 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is rejected as being rendered vague and indefinite by the language set forth in the preamble of the claim and in step a) of the recited method. It is unclear, whether Sir 2 is necessarily present in the reaction mixture.

Claim 176 is rendered vague and indefinite by the recitation of specific amino acid residues (lysine 9 and lysine 14) without providing a base sequence.

Claim 180 is rendered vague and indefinite by the recitation of specific amino acid residues (lysine 16) without providing a base sequence.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 and 169-208 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claims 11 and 191 to recite "...one or more acetylated amino acid side chains ...". This phrase does not appear in the specification, or original claims as filed.

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Applicant does not point out specific basis for this limitation in the application, and none is apparent. Therefore this limitation is new matter.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ROBERT A. ZEMAN
PATENT EXAMINER

November 9-2005